IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

VERTOS MEDICAL, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. H-12-3224
	§	
NOVITAS SOLUTIONS, INC.,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION SETTING OUT FINDINGS OF FACT AND CONCLUSION OF LAW DISMISSING FOR LACK OF SUBJECT MATTER JURISDICTION

This is a suit by a company whose sole business is marketing a medical procedure for relieving spinal compression. The company, Vertos Medical, Inc., challenges the decision by a Medicare Administrative Contractor, Novitas Solutions, Inc., to revise the Local Coverage Determination for the region that includes Texas to place the procedure in the "non-coverage" category for Medicare benefits. Vertos seeks a preliminary injunction requiring Novitas to reinstate the prior standard that allowed a Medicare beneficiary to seek coverage for the costs of Vertos's minimally invasive lumbar decompression, or ***MILD***, medical procedure. This court held an evidentiary hearing on the preliminary injunction application. Before the hearing, Novitas moved to dismiss for lack of subject-matter jurisdiction, and Vertos responded. At the hearing, both parties appeared through counsel and presented evidence. Counsel for both parties also presented arguments on the subject-matter jurisdiction issues.

Based on the pleadings, the motion and response, the record, the testimony of the witnesses, the exhibits admitted into evidence, the arguments of counsel, and the applicable law, this court

enters findings of fact and conclusions of law under Fed. R. Civ. P. 52. These facts and conclusions lead to the dismissal of this suit, and the denial of the injunctive and mandamus relief Novitas seeks, without prejudice, for lack of subject-matter jurisdiction.

I. The Parties and the Procedure

Vertos owns the ***MILD*** medical procedure for the treatment of lumbar spinal stenosis. Vertos was formed in 2005 to market the ***MILD*** procedure. The ***MILD*** procedure is approved by the Federal Drug Administration, which is a necessary, but not a sufficient, condition for Medicare coverage. The ***MILD*** procedure is billed with code CPT 0275T, a Category III billing code. Category III billing is generally used for medical services and procedures representing new or emerging technologies. The CPT codes are assigned by the American Medical Association. Vertos could, but has not, raise a protest with the AMA over the inclusion of the ***MILD*** procedure in Category III.

Medicare coverage decisions are made on both a national and a regional basis. A National Coverage Determination (NCD) is a determination by the Department of Health and Human Services Secretary about whether a particular item or service is covered by Medicare. *See* 42 U.S.C. § 1395ff(f)(1)(B). The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS) through private contractors — carriers or intermediaries — known as Medicare Administrative Contractors (MACs). 42 U.S.C. § 1395kk-1. One function of a MAC is to develop Local Coverage Determinations (LCDs). *Id.* § 1395kk-1(a)(4). An LCD is a determination by an MAC on whether a particular item or service will be covered by Medicare benefits on an intermediary or carrier-wide basis. All Medicare contractors must be consistent with the NCDs. *See* 42 C.F.R. § 405.1060(a)(4).

Medicare coverage is limited to items or services that are medically reasonable and necessary. 42 U.S.C. §§ 1395ff(f)(2)(B); 1395y(a)(1)(A). A determination that a Category III item or service is excluded from the non-coverage category does not mean that every beneficiary who seeks coverage will receive it. Such decisions are made on a case-by-case basis. But the determination to include an item or service in the non-coverage category in an LCD means that no beneficiary will receive such coverage. *See, e.g., Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 n.4 (5th Cir. 2011) (stating that "[a] carrier may automatically deny claims when a 'clear policy serves as a basis for denial' for that type of claim" and categorizing an LCD as setting forth such a policy).

Vertos markets the ***MILD*** procedure as a treatment option for patients suffering from lumbar spinal stenosis who, because of conditions such as diabetes or obesity, are not candidates for more invasive options like laminectomies. Most of the patients who have received the ***MILD*** procedure are Medicare recipients. The ***MILD*** procedure has been reviewed favorably in some studies published in peer-reviewed journals. At least half of those studies were funded by Vertos, and some of the other studies were conducted by physicians receiving financial support from Vertos. The record also contains one peer-review-journal study by physicians with no connection to Vertos reporting negative results after 18 months. Vertos disputes the reliability of this study.

As of May 2012, the country was organized into 15 regions for Medicare administration purposes, with a MAC for each region. Trailblazer Health Enterprises, LLC ("Trailblazer") was the MAC for Jurisdiction 4, which covered Colorado, New Mexico, Oklahoma, and Texas.[1] In 2011,

[1] Document No. 1, ex. D. In their Proposed Findings of Fact, Defendant states that Jurisdiction 4 covered Arkansas, Louisiana, and Texas. Document No. 23, ¶ 7. However, at the hearing, Dr. Debra Patterson, VP and Executive Medical Director for Novitas, testified that the Trailblazer LCD applied in Colorado, New Mexico, Oklahoma, and Texas. Exhibit D to Plaintiff's Complaint supports her testimony. Document No. 1, ex. D at 3.

all but one LCD placed the ***MILD*** procedure in the non-coverage category. In May 2012, Trailblazer changed its LCD to exempt the ***MILD*** procedure from the non-coverage category. At that time, 6 of the 15 regional MACs had LCDs allowing case-by-case coverage decisions for individual Medicare beneficiaries who had or intend to have the ***MILD*** procedure. No national insurance company has yet covered the ***MILD*** procedure.

In July 2011, Trailblazer had issued an LCD that included the ***MILD*** procedure in the non-coverage category. Individual Medicare beneficiaries brought claims against Trailblazer challenging the denial of benefits for the ***MILD*** procedure. In May 2012, after 11 favorable Administrative Law Judge decisions on claims by individual Medicare beneficiaries challenging the Trailblazer LCD's classification of the ***MILD*** procedure, Trailblazer exempted the procedure from the non-coverage LCD and began to evaluate claims for the ***MILD*** procedure on a case-by-case basis. At that time, Trailblazer was aware that it had lost the MAC contract, which had occurred in March 2012.

In the 2012 reorganization of the country's MAC regions, Jurisdictions 4 and 7, serviced by three MACs (Pinnacle, Cahaba, and Trailblazer), were consolidated to form a single expanded area, Jurisdiction H.[2] This new area includes Arkansas, Louisiana, Mississippi, Colorado, New Mexico, Oklahoma, and Texas.[3] Novitas Solutions, Inc. ("Novitas") is the MAC for the newly consolidated Jurisdiction H. As part of the reorganization and consolidation, CMS required the incoming MACs to review the policies of the outgoing MACs and select the most clinically appropriate policies to implement over the consolidated jurisdiction. Novitas reviewed LCDs from Trailblazer, Pinnacle, and Cahaba. At the end of June 2012, Novitas published the LCDs that it intended to implement

---

[2] *Id.*

[3] *Id.*

between August 13, 2012 and November 19, 2012, depending on the state. *See* Document No. 1, ex. D at 3. The Novitas LCD selected a Pinnacle LCD that included Category III procedures such as the ***MILD*** procedure in the non-coverage category. This approach reinstates the Trailblazer LCD approach to the ***MILD*** procedure that had been in place from July 2011 to May 2012, when Trailblazer exempted the ***MILD*** procedure from the non-coverage category. The new LCD has been evaluated by the Department of Health and Human Services and found consistent with the NCD.

Since the consolidation, there are ten operational MACs administering Medicare claims. Of the ten, six have LCDs in place that address the ***MILD*** procedure code. Two of the LCDs cover the procedure, four do not provide for coverage, and the remaining four do not address this procedure. In those four jurisdictions, the coverage determination is on a case-by-case basis.

In this lawsuit, Vertos asks this court to require Novitas to reinstate the May 2012 Trailblazer LCD provision that excluded the ***MILD*** procedure from the non-coverage category in the LCD for Texas. Novitas argues that Vertos has no standing to seek this relief and that this court has no authority to grant it.

II. The Procedure for Administrative and Judicial Review of LCDs

A Medicare beneficiary whose claim is denied may pursue review either through a claims-appeal process under 42 U.S.C. § 405(g) or by seeking review of an LCD, or both. 42 U.S.C. §§ 1395ff(f)(2,5). Challenging an LCD allows review of an entire provision rather than only the specific claim denial. An LCD challenge is reviewed by an administrative law judge under a reasonableness standard. *See* 42 U.S.C. § 1395 ff(f)(2)(A); 42 C.F.R. § 426.300(a). A beneficiary's challenge to an individual claim denial is reviewed de novo. *See* 42 C.F.R. § 405.1000(d). The beneficiary can seek review of an adverse ALJ decision before the Departmental Appeals Board of

the Department of Health and Human Services. 42 U.S.C. § 1395ff(f)(2)(A)(ii). A decision of the Departmental Appeals Board is a final agency action and is subject to judicial review. *Id.* § 1395ff(f)(2)(A)(iv).

A patient may challenge coverage determinations through the administrative-review process if the patient is entitled to benefits under Part A or enrolled under Part B of Medicare, and in need of the items or services that are the subject of the coverage determination. *See id.* § 1395ff(f)(5). Vertos is neither a beneficiary nor a provider and cannot itself access the administrative-review process to challenge the Novitas LCD. Yet the structure of Medicare makes that administrative-review process necessary to a district court's subject-matter jurisdiction.

Vertos is invoking federal subject-matter jurisdiction and has the burden to establish that it is present. *See Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir.1981). Federal Rule of Civil Procedure 12(b)(1) governs challenges to a court's subject-matter jurisdiction. "A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir.1998) (quoting *Nowak v. Ironworkers Local 6 Pension Fund*, 81 F.3d 1182, 1187 (2d Cir.1996)). "Courts may dismiss for lack of subject matter jurisdiction on any one of three bases: (1) the complaint alone; (2) the complaint supplemented by undisputed facts in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Clark v. Tarrant County*, 798 F.2d 736, 741 (5th Cir.1986) (citing *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir.1981)). When examining a factual challenge to subject-matter jurisdiction under Rule 12(b)(1), which does not implicate the merits of plaintiff's cause of action, the district court has substantial authority "to weigh the evidence and satisfy itself as to the existence of its power to

hear the case." *Garcia v. Copenhaver, Bell & Assocs.*, 104 F.3d 1256, 1261 (11th Cir.1997); *see also Clark*, 798 F.2d at 741. Matters outside the pleadings, such as testimony and affidavits, are appropriately considered. *See Garcia*, 104 F.3d at 1261.

A. Administrative Channeling Under the Act

The Fifth Circuit has recently described the "administrative channeling" effect of the structure of the Medicare Act as one that "severely restricts the authority of federal courts by requiring "virtually all legal attacks" under the Act be brought through the agency. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000). *Physician Hospitals of America v. Sebelius*, 691 F.3d 649, 653 (5th Cir. 2012). In *Physician Hospitals*, a trade group and a physician-owned hospital sued the Secretary of HHS for declaratory and injunctive relief from an allegedly unconstitutional provision of the Patient Protection and Affordable Care Act that limited Medicare reimbursement for services furnished to patients referred by a physician-owner. The Secretary moved to dismiss for lack of subject-matter jurisdiction on the basis that the plaintiffs had failed to proceed with statutorily mandated administrative procedures before seeking judicial review of their claims. The plaintiffs explained that they went directly to the courts because, in order to file an administrative claim, they would have had to complete a new hospital building and treat a patient in that building. To do so would have risked millions of dollars because the building had been stopped when the challenged law was enacted. The Fifth Circuit explained that despite the costs and delays of administrative review, it was nonetheless a statutorily mandated requirement for the federal court's ability to consider the claims.

Section 405(h), a provision of the Social Security Act incorporated into the Medicare Act by 42 U.S.C. § 1395ii, states:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). Once the Secretary reaches a final decision, an individual who was a party to the administrative proceeding "may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the [Secretary] may allow." 42 U.S.C. § 405(g).

The Fifth Circuit summarized the effect of § 405(h): "judicial review of such a claim is available only after a party first presents the claim to the Secretary and receives a final decision." *Physician Hospitals*, 691 F.3d at 653. The court then reviewed the case law interpreting this "administrative channeling" provision, including four Supreme Court opinions. The first, *Weinberger v. Salfi*, 422 U.S. 749 (1975), emphasized that § 405(h) was more than a "codified requirement of administrative exhaustion." Instead, "it provide[d] both the standing and the substantive basis" for claims, including constitutional challenges. *Id.* at 760-61. In *Heckler v. Ringer*, 466 U.S. 602 (1984), the Court emphasized that the channeling provision applied to claims for declaratory and injunctive relief as well as challenges to benefit denials. In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), the Court considered a situation in which there was neither administrative nor judicial review available for the claim. In that case, the Court acknowledged that the unavailability of any review at all would have raised constitutional issues that the Court avoided in that case. In the most recent case, *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000), the Court considered when the exception to administrative channeling, a

"complete preclusion of judicial review," applied to allow a party to litigate in federal court without first presenting the claim to the Secretary. The Court emphasized that this exception arose only when applying § 405(h) would not simply "channel[] review through the agency, but would mean no review at all." *Id*. at 16-17.

The cases, including appellate court cases following *Illinois Council*, make it clear that "delays in the administrative process," or hardships related to the delay, are not sufficient to allow parties like Physician Hospitals or Vertos to proceed directly to federal court. Instead, there has to be "'complete preclusion'" or a "serious 'practical roadblock' to having their claims reviewed in any capacity, administratively of judicially." *Physician Hospitals*, 691 F.3d at 655. The delays and costs of such administrative channeling was one that "Congress was aware it was imposing on health-care providers":

> In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified. In any event, such was the judgment of Congress as understood [by the Court].

Id. at 653 (quoting *Illinois Council*, 529 U.S. at 13).

In *Physician Hospitals*, the Fifth Circuit concluded that *Illinois Council* did not except administrative channeling even when administrative review would require extraordinary expenses that a plaintiff could not recover if its claim proved unsuccessful. The fact that the party would itself suffer great hardship was not enough. Instead, there had to be either a legal impossibility that any claimant would obtain judicial or administrative review, or hardship from administrative channeling that was "sufficiently widespread" to threaten the loss of any judicial review. The second exception applied when there was no third party with an interest and a right to seek administrative review. If

others had an incentive, and were properly aligned to bring an administrative challenge, the claimant's inability or difficulty would not trigger the *Illinois Council* exception. 691 F.3d at 657-658.

The Fifth Circuit concluded by noting that the costs, burdens, and inefficiencies of this approach were not a basis for a different result. Congress had recognized, and accepted, that the channeling requirement "comes at a price." *Id.* at 659 (quoting *Illinois Council*, 529 U.S. at 13). That price "may seem justified," however, "[i]n the content of a massive, complex health and safety program such as Medicare." *Id.* In any event, a change in the structure for judicial review had to come from Congress, not from the courts.

B. Analysis

1. Federal Question Jurisdiction

Because Vertos's claim "arises under" the Medicare Act, this court lacks jurisdiction under § 405(h) unless Vertos overcomes that provision by showing a complete bar to judicial review. The record is clear that this requirement is not met. Even when a plaintiff cannot access the administrative-review process, the possibility of review is not completely precluded as long as third parties, such as physicians or beneficiaries, have the ability and incentive to access the administrative review channel. *Physician Hospitals*, 691 F.3d at 657-58; *Nat'l Athletic Trainers' Ass'n v. Dept. of Health and Human Servs.*, 455 F.3d 500 (5th Cir. 2006) (holding that the *Illinois Council* exception did not apply and the district court lacked subject-matter jurisdiction over the claim by the defendant, an association of athletic trainers, when physicians could access administrative remedies and had sufficient incentive to do so).

The record is clear that beneficiaries have the incentive and are aligned to challenge the Novitas LCD. *See* 42 U.S.C. §§ 1395ff(f)(2,5). The May 2012 challenge brought against the Trailblazer LCD, and the large number of beneficiaries challenging individual claim denials, indicate that beneficiaries are motivated to challenge the current LCD. After proceeding through the administrative channel, the challenger would have access to judicial review, if necessary. *Id.* 1395ff(f)(2)(iv). Review is not completely precluded. *Nat'l Athletic Trainers' Ass'n*, 455 F.3d at 504-05.

Vertos relies on *DeWall Enterprises, Inc. v. Thompson,* 206 F. Supp. 2d 992 (D. Neb. 2002), to argue that review is precluded here because the Secretary refuses to implement administrative review decisions in favor of the plaintiff. The record does not support this argument. The prior challenge to the LCD that placed the ***MILD*** procedure in the non-coverage category was not brought against Novitas, but against its predecessor, Trailblazer. The record also reflects administrative review decisions that do not favor the beneficiary seeking coverage of the ***MILD*** procedure. The record shows that when individual beneficiaries succeed in their administrative claims, the MAC pays for the ***MILD*** procedure. The facts that Trailblazer changed its LCD in the face of a beneficiary's challenge, and that Novitas chose to use another MAC's LCD that followed the approach to the ***MILD*** procedure Trailblazer previously had in place, are not sufficient to conclude that Novitas acted contrary to the regulations or that Novitas (or the Secretary) has made review practically or legally unavailable.

Vertos also argued that the decision to place the ***MILD*** procedure in the non-coverage category is so wrong—so lacking in medical support—that judicial review is required. The strength of the administrative claim on the merits does not provide a basis for avoiding administrative review

or trigger the *Illinois Council* exception to administrative channeling. This court lacks federal-question jurisdiction to hear Vertos's claims. *Illinois Council*, 529 U.S. at 20-21.

2. Other Sources of Subject Matter Jurisdiction

The Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, does not provide an independent grant of jurisdiction. *Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449, 457-58 (1999). Vertos relies on mandamus as the primary alternative basis for jurisdiction, because § 405(h) does not bar mandamus jurisdiction. *Wolcott*, 635 F.3d at 764 ("We join the near unanimity of all other circuits holding § 405(h) does not preclude mandamus jurisdiction to review otherwise unreviewable procedural issues."). But mandamus does not provide a basis for this court to act.

Under the Mandamus and Venue Act, a district court has "jurisdiction [over] any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Section 1361 does not grant jurisdiction for courts to grant relief other than mandamus, such as preliminary injunctions. *Wolcott*, 635 F.3d at 766. In *Wolcott*, the plaintiff sought review of the district court's dismissal of five claims for mandamus relief. The Fifth Circuit found that it had subject-matter jurisdiction over Counts I, II and IV because the ultimate relief the plaintiff sought in each count was an order compelling the defendants to perform a nondiscretionary duty. *Id.* Count I asked the district court to compel the defendants to pay claims in accordance with final administrative decisions, Count II sought to compel defendants to adhere to payment deadlines set by the Medicare Claims Processing Manual, and Count IV sought to compel defendants to remove the plaintiff from prepayment review as required by the Code of Federal Regulations. However, the circuit court found that there was no

subject-matter jurisdiction as to Counts III and V because those counts asked the district court to compel the defendant to cease doing an injurious action in the future. *Id.* at 767. Count III sought to compel defendants to stop denying new claims for reasons held invalid in previous administrative decisions and Count V sought to compel defendants to stop automatically denying claims that exceeded five per patient per year.

In this case, Vertos is asking this court to prevent Novitas from implementing its new LCD so that the ***MILD*** procedure will continue to be covered under Medicare in the future. Like Counts III and V in *Wolcott*, the relief Vertos seeks in this case is based on an alleged record of reasons for denial held invalid by previous administrative decisions and asks the court to compel the defendant to stop committing allegedly injurious future acts. Vertos is asking this court to prevent Novitas from implementing its new LCD so that the ***MILD*** procedure will continue to be covered under Medicare in the future. Because Vertos asks the court to compel Novitas to restore the status quo and to avoid committing future injurious acts, this is a request for injunctive relief, not mandamus. *See Wolcott*, 635 F.3d at 766.

As the Fifth Circuit noted in *Wolcott*, "[a]n injunction 'is a remedy to restrain the doing of injurious acts' or to require 'the undoing of injurious acts and the restoration of the status quo,' whereas 'mandamus commands the performance of a particular duty that rests on the defendant or respondent, by operation or law or because of official status.'" *Id.* (quoting 42 Am. Jur. 2d *Injunctions* § 7). The decision Vertos challenges—whether to place the ***MILD*** procedure in the non-coverage category of items and services—is one that has divided MACs and provoked disagreement within the medical research community. It can hardly be described as a ministerial duty "so plainly prescribed as to be free from doubt," as required for mandamus to issue. *See Bailey v. Mutual of*

Omaha Ins. Co., 534 F. Supp.2d 43, 52 (D.D.C. 2008) (finding no mandamus jurisdiction as alternative to administrative channeling to allow district court to consider challenge to continued enforcement of an LCD to deny certain claims) (quoting *Consol. Edison Co. v. Ashcroft*, 286 F.3d 600, 605 (D.C. Cir. 2002)); *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 34 (1980). This court lacks subject matter jurisdiction over Vertos's claim for mandamus relief.

III. Conclusion and Order

Vertos's complaint is dismissed for lack of subject matter jurisdiction.

SIGNED on November 27, 2012, at Houston, Texas.

Lee H. Rosenthal
United States District Judge